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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,169

12/07/2004

Marlen Andreevich Sulamanidze

2185-192

2936

6449

7590

08/19/2008

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SUITE 800

WASHINGTON, DC 20005

EXAMINER

EREZO, DARWIN P

ART UNIT

PAPER NUMBER

3773

NOTIFICATION DATE

DELIVERY MODE

08/19/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No. 10/517,169	Applicant(s) SULAMANIDZE ET AL.	
	Examiner Darwin P. Erez	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6 and 8-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6 and 8-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/6/08 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 6 and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,241,747 to Ruff, and as evidenced by US 3,221,746 to Noble and US 5,921,995 to Kleshinski.

Ruff discloses a surgical thread capable for use in cosmetic operations made of a polymeric material (col. 4, lines 29-31), containing successively arranged along its length inclined notched protrusions made in the form of conical barbs **6** with pointed flexible and elastic ends (see Figs. 1 and 2), the barbs positioned on several sides along the section of the thread with a successively alternating inclination; wherein the elevation of the barb ends is less than the diameter of the thread (seen in Fig. 2); wherein the interval between the barbs are less than two diameters of the thread (as seen in Figs. 1-2); wherein the notched barbs are provided on two opposite sides of the thread, the direction of their inclination being opposite as well (Fig. 3); wherein barbs are provided on two sides with an alternating direction of their inclination (Fig. 4); wherein the barbs are positioned in a staggered order along the thread (Figs. 1-2); and wherein the surgical thread is fully capable of lifting a flabby droopy region of soft tissues of the face in use.

Ruff discloses all the limitations of the claims except for the notched protrusions being provided in form of needles with sockets for fixation on the thread. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to separate the barbs from the suture thread using sockets or any other attachment means because it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *In re Dulberg*, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961).

Furthermore, it is noted that barbs are known in the art to be formed as a separate element from the main structure, as evidenced by the Noble reference (see

Figs. 1-3) and even the Kleshinski reference (collar 14 includes barbs). Since integrated barbs or separated barbs have now been shown to be well known variants in the art, one of ordinary skill in the art would still have found it obvious to construct a formerly integral structure in various elements since it merely involves only routine skill in the art. Moreover, simple substitution of one known element (integrated barbs) with another known element (separated barbs) will provide predictable results (such as a working barbed suture). *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007).

Response to Arguments

5. Applicant's arguments filed 6/6/08 have been fully considered but they are not persuasive.

In response to applicant's argument that the modified device of Ruff is not used in cosmetic surgery, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. As such, the device of Ruff is fully capable of being used in cosmetic operations, such as to close wounds or to lift tissues.

As the claim 6, the applicant argued that the use of sockets preserve the rupture strength of the thread. However, the device of Ruff, as shown in Figs. 1-3, also preserves the rupture strength of the thread since the barbs are not provided as cut slits on the thread. That is, the thread maintains a consistent diameter along its length with

the barbs extending from the cylindrical thread without any structure that will weaken the rupture strength of the thread. Therefore, the modification to provided the barbs as a separate structure from the thread will also preserve the rupture strength of the thread.

It is again noted that barbs/protrusions in medical devices can be formed as an integral part of the medical device, as taught by Ruff, or as separate structures attached to the medical device, as taught by Noble and Kleshinski. Furthermore, the case law, *In re Dulberg*, states “constructing a formerly integral structure in various elements involves only routine skill in the art”.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3773

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erez/
Primary Examiner, Art Unit 3773